

St. John's University/
Myovant Sciences

Pharmaceutical Industry Fellowship



in partnership with:



**ST. JOHN'S
UNIVERSITY**

College of Pharmacy
and Health Sciences

**Early Clinical
Development**

**Clinical
Regulatory Affairs**

**Commercial
Regulatory Affairs**

2023- 2025

Redefining Care

FOR WOMEN FOR MEN FOR YOU



About Myovant Sciences



At Myovant, our mission is to **redefine care** by ensuring that everyone, regardless of gender, has the information, the medicines, and the resources they need to improve their health and reach their full potential.

We aspire to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy.

Purpose-driven Science



Driving Innovative research

We aim to advance science that holds promise to improve people's lives.

Empowering Medicines



Addressing Unmet need

We are focused on developing new medicines for common diseases with limited treatment options.

Transformative Advocacy



Forging change

We are committed to a healthier and more equitable future for all women and men.

WHERE WE CALL HOME

We're a growing global healthcare company. Our offices are in Brisbane, California, and Basel, Switzerland, two of the leading hubs for biotech and pharma in the world.

Our US office in Brisbane is in the heart of Silicon Valley, surrounded by top universities and institutions. Our Brisbane team leads our US activities.

Our expanding global headquarters is in Basel, a city known for both its dynamic innovation sector and rich arts and culture.



Brisbane, California



Basel, Switzerland

“Home to scholars and scientists who are **unified by one intrepid goal**—to improve the quality of life for people globally.”



About St. John's University

St. John's University College of Pharmacy and Health Sciences, located in Queens, NY, is affiliated and partners with a number of elite healthcare organizations throughout the New York metropolitan area. Founded in 1870, the College offers undergraduate and graduate level healthcare-related programs. Undergraduates and graduates are actively involved in basic science, clinical research, and providing patient-centered care to an urban patient population.

Dean	Anne Y. F. Lin '84P, '86Pharm.D., FNAP
Location	Queens, NY
Graduate Programs Offered Through the University	<ul style="list-style-type: none">• M.S./Ph.D. in Pharmaceutical Sciences• M.S in Biological and Pharmaceutical Biotechnology, Pharmacy Administration, and Toxicology• Masters of Business Administration (MBA)• Masters of Public Health (MPH)• M.S. in Data Mining and Predictive Analytics

About Our Fellowship

The St. John's University/Myovant Sciences Fellowship Program is a brand-new program, offering one of the most dynamic and challenging development programs in the industry. We offer 2-year fellowships focused in Early Clinical Development, Clinical Regulatory Affairs, and Commercial Regulatory Affairs. Fellows are offered the opportunity to rotate to other functional areas during the second year of the fellowship. The programs are based remotely and are designed to offer a broad range of hands-on training and professional development opportunities.



Joseph Brocavich, PharmD
*Senior Associate Dean
for Pharmacy Programs*

ST. JOHN'S UNIVERSITY COMPONENT

Fellows are full-time University employees and are provided a competitive stipend and benefits package. Each fellow is required to complete a one-semester teaching component at the University and a collaborative research project. Additionally, each fellow is able to participate in a number of other professional and educational development opportunities at the University, including precepting pharmacy students; continuing education courses; resident and fellow seminars; Affiliate Faculty appointments; and a teaching certificate course. Fellows may also enroll, with a tuition remission benefit, and participate in University courses and graduate degree programs.

CERTIFICATE OF COMPLETION

Upon successful completion of the program, Fellows will receive a certificate from St. John's University College of Pharmacy and Health Sciences and Myovant Sciences.

Website: [www.stjohns.edu/
resources/places/pharmaceutical-
industry-fellowship-programs](http://www.stjohns.edu/resources/places/pharmaceutical-industry-fellowship-programs)

Early Clinical Development

Early Clinical Development (ECD) is responsible for the development and execution of early clinical development project plans from first-in-human to phase 1b/2a, including clinical pharmacology and biopharmaceutical studies, as well as model-informed drug development (MIDD) across the men's and women's health programs at Myovant.



Fellow Roles and Responsibilities

- Provide clinical pharmacology and scientific input into early clinical development plans
- Contribute to the preparation of early clinical development components of regulatory documents, including Investigational New Drug Applications (INDs), Investigational Medicinal Product Dossiers (IMPDs), Clinical Trial Applications (CTAs), and submission documents
- Provide scientific input into the rationale, study design, and study assessments/procedures for early clinical development studies, including coordination with pharmacometrics, bioanalytics, and biostatistics
- Collaborate with the early clinical development operations team to support development of clinical study protocols and study-related activities during the initiation, execution, and close-out of early clinical development studies
- Collaborate with cross-functional study teams to provide oversight and management of early clinical development studies
- Contribute to the interpretation of clinical, pharmacokinetic, pharmacodynamic, and safety data from early clinical development studies, including co-authoring and review of clinical study reports
- Support early development teams (EDTs) by participation in team and subteam meetings, including preparation of scientific content relevant to strategic decision-making



Elizabeth Migoya, PharmD
*Vice President,
Early Clinical Development
Fellowship Co-Director
& Lead Preceptor*



Wayne Chen, PharmD
*Director,
Clinical Pharmacology
Preceptor*

FELLOWSHIP SCHEDULE

Year 1	Early Clinical Development (Months 1-12) The PharmD fellow will rotate through 3 focused areas within ECD including clinical pharmacology, early clinical development operations, and pharmacometrics.
Year 2	Elective Rotations (Months 13-24) The PharmD fellow may either choose to continue to gain additional experience within ECD or rotate through other departments, such as regulatory affairs.

Clinical Regulatory Affairs

Our Global Regulatory Strategy team leads our Company's business-critical relationships with the U.S. Food and Drug Administration (FDA) and other regulatory agencies, ensuring the continued success of our product portfolio and pipeline.



Fellow Roles and Responsibilities

- Develop a comprehensive understanding of global regulations, guidances related to drug development, and the regulatory environment
- Support cross-functional product teams by offering strategic guidance on regulatory requirements and design a regulatory strategy for development and market registrations
- Ensure Investigational New Drug Applications (INDs), New Drug Applications (NDAs), Marketing Authorization Applications (MAAs), and Clinical Trial Authorizations (CTAs) are maintained in compliance with local regulatory requirements
- Interact with internal and external stakeholders to ensure company compliance with all appropriate federal regulations and guidances
- Develop a thorough understanding on how to best conduct health authority meetings and prepare teams for effective regulatory interactions



Amjad Iqbal, PharmD
*Vice President,
Regulatory Affairs
Fellowship Co-Director
& Lead Preceptor*



Lilly Justus, PharmD
*Senior Manager,
Clinical Regulatory Affairs
Preceptor*

FELLOWSHIP SCHEDULE

Year 1	Clinical Regulatory Affairs (Months 1-12) The PharmD fellow will spend the first year working within Clinical Regulatory Affairs on challenging and meaningful programs.
Year 2	Elective Rotations (Months 13-24) The PharmD fellow will rotate through various functional areas within the company, outside of Clinical Regulatory Affairs. These rotations will be approximately 3 to 6 months in duration. Elective rotations are chosen by the Fellow based on his or her area of interest, along with preceptor availability.

Commercial Regulatory Affairs

Our Commercial Regulatory Affairs team is responsible for providing strategic, high quality, timely and decisive regulatory advice on the approval of advertising and promotional materials and other product and disease-state related materials, in accordance with FDA regulations, company policies, and business objectives. In addition, the Commercial Regulatory Affairs group liaises with the Office of Prescription Drug Promotion (OPDP) at the US Food and Drug Administration (FDA) for matters pertaining to advertising and promotion of Myovant Science's products.



Fellow Roles and Responsibilities

- Provide Myovant's internal stakeholders with strategic regulatory advice on advertising and promotional materials, in accordance with FDA regulations and business goals
- Gain insight into marketing's goals and objectives and understand how those measures are reflected in the development of product advertising
- Develop a comprehensive understanding of FDA regulations regarding drug advertising and promotion
- Apply regulations to the development of product promotion (including, but not limited to, television commercials, social media advertisements, website design, and print brochures)



Amy Toscano, PharmD
*Senior Director,
Commercial Regulatory Affairs
Lead Preceptor*



Kim Do, PharmD
*Senior Manager,
Commercial Regulatory Affairs
Preceptor*

FELLOWSHIP SCHEDULE

Year 1	Commercial Regulatory Affairs (Months 1-12) The PharmD fellow will spend the first year within Commercial Regulatory Affairs.
Year 2	Elective Rotations (Months 13-20) The PharmD fellow will rotate through various functional areas within the company, outside of Commercial Regulatory Affairs. These rotations will be approximately 3 to 6 months in duration. Elective rotations are chosen by the Fellow based on his or her area of interest, along with preceptor availability. Commercial Regulatory Affairs (Months 21-24) The PharmD fellow will return to Commercial Regulatory Affairs for the final three months of the program.

Program Leadership

ST. JOHN'S UNIVERSITY

Joseph Brocavich, PharmD
*Senior Associate Dean
for Pharmacy Programs*



MYOVANT SCIENCES

Juan Camilo Arjona Ferreira, MD
*Chief Medical Officer
Executive Sponsor*

EARLY CLINICAL DEVELOPMENT

Elizabeth Migoya, PharmD
*Vice President,
Early Clinical Development
Fellowship Co-Director
& Lead Preceptor*



Wayne Chen, PharmD
*Director,
Clinical Pharmacology
Preceptor*

CLINICAL REGULATORY AFFAIRS

Amjad Iqbal, PharmD
*Vice President, Regulatory Affairs
Fellowship Co-Director
& Lead Preceptor*



Lilly Justus, PharmD
*Senior Manager,
Clinical Regulatory Affairs
Preceptor*

COMMERCIAL REGULATORY AFFAIRS

Amy Toscano, PharmD
*Senior Director,
Commercial Regulatory Affairs
Lead Preceptor*



Kim Do, PharmD
*Senior Manager,
Commercial Regulatory Affairs
Preceptor*

Application Process

Interviews will be conducted virtually and on a rolling basis beginning on October 31, 2022. It is highly encouraged to visit our booth at ASHP Midyear, December 5th-6th, 2022.

Eligibility Requirements

To be considered for the St. John's University/Myovant Sciences Pharmaceutical Industry Fellowship Program, you must meet the following requirements:

- Graduate of an Accreditation Council for Pharmacy Education (ACPE)-accredited Doctor of Pharmacy Program prior to the start of the fellowship term
- Have a strong interest in pursuing a career in the pharmaceutical industry
- Eligible to work in the United States

Deadlines

November 14, 2022	<ul style="list-style-type: none">• Curriculum Vitae (CV)• Letter of Interest
November 21, 2022	<ul style="list-style-type: none">• College Transcript• Three Letters of Recommendations

SEND ELECTRONIC COPIES TO:

Dr. Joseph Brocavich: stjfellowships@stjohns.edu



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